REMARKS

Claims 1, 4-19, and 21-23 are of record pending in this application.

Claim Objections

Claim 5 stands objected to for reciting the phrase "selected from the group consisting essentially of". The Examiner argues that the phrase as written encompasses not only the quenchers recited but also unknown quenchers not listed. Claim 5 has been amended to recite the phrase "selected from the group consisting of".

Claims 1, 10, 11, 15, 16, 21 and 23 are objected to for the use of the terms "riboflavin photosensitizer", "riboflavin" and "photosensitizer" for being inconsistant. Applicants have amended these claims to recite the Examiner's suggested claim language.

Claim 21 is objected to for not using the phrase "pathogen-reduced" and "by". Claim 21 has been amended to recite the Examiner's suggested language.

Withdrawal of these objections is respectfully requested.

Claim Rejections

35 USC 112

Claims 4, 6, 9, 11-19, 22, and 23 stand rejected under 35 USC §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The Examiner rejected claims 4, 6, 9, 22, and 23 for reciting the limitation "the fluid" which has no antecedent basis. Applicants have amended these claims to replace "fluid" with "blood components and riboflavin acting as a photosensitizer".

Independent claim 11 stands rejected for reciting the phrase "substantially maintaining the damage to the nucleic acids" as being unclear. Applicants respectfully disagree with this

rejection. As described on page 8, line 1 of Applicants' specification, "substantially maintaining the damage means that the damage sustained by the nucleic acids of pathogens is maintained over time so that when the blood product, which has been treated with riboflavin and light is transfused into a recipient, the inactivated pathogen will not self-repair the damaged nucleic acids and reproduce in the transfusion recipient." Reconsideration of this rejection is respectfully requested.

Applicants thank the Examiner for withdrawing the previous rejections of claims 1, 4-7, 9, 10, 21-23 under 35 U.S.C. §112, first paragraph, written description and enablement.

However, claims 1, 4-19 and 21-23 currently stand rejected under 35 USC §112, first paragraph, as failing to comply with the enablement requirement. The Examiner feels that the specification does not enable a process for preventing self repair of nucleic acids of pathogens as claimed in claim 1; preventing reactivation of white blood cells, as claimed in claim 11; or preventing white blood cells, bacteria or viruses from reproducing as claimed in claim 21.

Applicants respectfully disagree. As described on page 7, beginning on line 27, "repair is defined as the molecular processes that are the basis for pathogen reactivation. Reactivation, or the synonymous term recovery, is defined as the regaining of, by a damaged pathogen, the capability to propagate..." Fig. 7 shows a graph of log/mL virus reactivation in response to riboflavin concentration. As can be seen from Fig. 7, irradiation of virus with riboflavin and light prevents reactivation of viral DNA. Applicants believe this data enables Applicants independent claim 1 and the dependent claims that depend therefrom.

As described in Example 3, beginning on page 12, exposure of the white blood cells (as represented by Jurkat cells) to riboflavin and light fragmented the nucleic acids. Fragmenting the DNA causes damage to the nucleic acids of the white blood cells. The phrase "to prevent re-activation of the white blood cells" has been deleted. Applicant believes Example 3 enables currently amended independent claim 11 and the dependent claims that depend therefrom.

Applicants have amended claim 21 to delete the phrase "suitable for re-infusion into a patient" in the preamble and "to prevent them from reproducing in the blood or blood component after reinfusion into the patient".

Applicants further disagree with the Examiner's interpretation of Fig. 4 and his claim that "... not all cells are prevented from self-repair since the percentage of cells after treatment with either UV in the presence of riboflavin stays at mere 36.1% in day 1 and 87.5% in day 2 which suggests that there is ongoing repair of the nucleic acid damages."

As described on page 12, line 11, percent positive signifies positive DNA damage. Upon treatment with riboflavin and UV light 36.1 % of the DNA in the treated cells was damaged, while on day 2, 87.5% of the treated cells manifested DNA damage. The damage went up from 36.1% initially to 87.5%. Applicants are not claiming that all of the pathogens present in the blood components are prevented from self-repair. Applicants are claiming that the damage is substantially maintained. Substantially maintained means that any damage sustained by the nucleic acids of pathogens is maintained over time (see page 8, line 1). Applicants' data supports this claim. Reconsideration of this rejection is respectfully requested.

35 USC §102

Claims 1, 6-8, 11-14, 16-19, 21 and 23 stand rejected under 35 USC §102(e) as being anticipated by Goodrich et al (US patent no. 6258577).

Applicants disagree that the claimed limitation "prevention of self-repair of the nucleic acids" is inherent in the Goodrich disclosure. There is nothing in the Goodrich reference to suggest that nucleic acids exposed to riboflavin and light are unable to self-repair. As set forth in *EMI Group North America, Inc. v. Cypress Semiconductor Corp,* 268 F.3d 1342, 60 USPQ2d 1423 (Fed. Cir. 2001) which referenced *Continental Can Co. v. Monsanto Co.* "[t]o serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill."

The Examiner does not point out where in the Goodrich reference he finds support for his position, nor does he use extrinsic evidence. As stated above, the Goodrich reference does not suggest that irradiating blood with riboflavin and light prevents self repair of the pathogenic nucleic acid. There is nothing in Goodrich that would inherently anticipate the claims.

35 USC §103

Claims 1, 4-8, 10-14, 16-19, 21 and 23 stand rejected under 35 USC §103(a) as being unpatentable over Goodrich et al[1] (US patent no. 6258577) in view of Goodrich et al[2] (WO/2002/096471, Viral Inactivation Process Using Antioxidant).

As set forth in MPEP 2141 II. The framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.* 383 U.S. 1, 148 USPQ 459 (1966). The factual inquiries enunciated by the Court are as follows:

A.) Determining the scope and content of the prior art

B.) Ascertaining the differences between the claimed invention and the prior art

C.) Resolving the level of ordinary skill in the pertinent art

As discussed above, Goodrich[1] does not teach or suggest "irradiating the blood components and riboflavin with light to fragment the nucleic acid of the pathogenic white blood cells, bacteria or viruses to prevent self repair of the nucleic acids. Neither does Goodrich[2]. Goodrich[2] discloses an additive solution for irradiating a blood component comprising riboflavin and a quencher. It does not suggest that irradiating blood components with the additive solution would prevent the self-repair of the nucleic acids. One skilled in the art would not assume that just because the nucleic acids of pathogens was exposed to riboflavin and light, that the damage was maintained over time such that the pathogens will not reproduce in the blood components as in Applicants' current invention.

Applicants respectfully request the Examiner to withdraw his rejections and to allow this application to issue. If there are any questions, or if prosecution can be expedited in any manner by a telephone conference, the Examiner is urged to call Applicants' representative at the below telephone number.

It is believed no fee is required for this filing. If this belief is incorrect, the Commissioner is authorized to charge the fee to Deposit Account 032316.

Respectfully submitted,

12-01-2008
Date

Laura Butterfield Arciniegas
Reg. No: 47,466
Telephone: (303) 231-4270